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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,610	12/21/2001	Stephen Quirk	15829	9118
22827 7590 07/06/2007 DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			EXAMINER RAMILLANO, LORE JANET	
			ART UNIT 1743	PAPER NUMBER
			MAIL DATE 07/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/026,610	<b>Applicant(s)</b> QUIRK ET AL.	
	<b>Examiner</b> Lore Ramillano	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 113-129 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 113-129 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/21/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

1. In applicant's reply filed on 4/19/07, applicant amended claim 113. Claims 113-129 are pending and under examination in the application.

### ***Response to Amendment***

#### ***Claim Rejections - 35 USC § 112***

2. The rejection of claims 113-129 under 35 U.S.C. 112, first paragraph, is withdrawn.
3. The rejection of claims 113-129 are rejected under 35 U.S.C. 112, second paragraph, is withdrawn.

### ***Drawings***

4. The objection to the drawings under 37 CFR 1.83(a) is withdrawn.

### ***Prior art rejections***

5. The rejection over the prior art is maintained.

#### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

#### ***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. **Claims 113-129** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oberhardt ('133), as previously cited.

Oberhardt discloses an analytical device, which comprises all of the presently recited features. Specifically, see Figures 1-4B and 11A(1)-11C of Oberhardt depicting an assay device comprising a test element (30) and a means for inducing a pressure differential (i.e. syringe) for driving sample fluid to and from the test element. The surface of test element (30) is optically analyzed after contact with the sample (e.g. column 6, lines 20-25).

Regarding the recited limitation that the test surface is a diffraction based surface, including binders printed thereon, see Oberhardt at column 9, first paragraph, teaching that specific binding partners are immobilized on the test surface for interaction with sample analyte. Such immobilization of binding partners is the only definition given by the instant specification for a "diffraction based" surface, and the anticipating structure of Oberhardt therefore implicitly anticipates any presently recited intended use.

Regarding the recited means for inducing a pressure differential as comprising either a positive or negative pressure inducement, see Oberhardt at Figures 4A and 4B disclosing both options.

Regarding the recited means for informing a user that a particular position has been reached, note Figure 3 of Oberhardt. The depicted syringe includes a syringe piston having a diameter greater than the distal end of the syringe chamber. As such, the abutment of the syringe piston at the end of its stroke would have provided an indication of its position.

Regarding the recited means for separating and means for diluting, see Oberhardt at column 9, lines 61-65, and column 16, lines 5-8, respectively, teaching these features.

Regarding the recited diffraction enhancing elements, see Oberhardt at column 9, first paragraph, teaching the presence of either magnetic or glass beads. Such beads would have inherently constituted diffraction enhancing elements.

Regarding the recited feature that the test element is removable, see Figure 3 of Oberhardt depicting the test element as connected to the syringe via a luer fitting. Such fitting would have rendered the element removable from the syringe. See also column 6, lines 2-25, disclosing operation of the device as including placing the test element in the testing device, which implies also that the test element can be subsequently removed.

Regarding the recited capillary, see Oberhardt at column 6, lines 45-53 disclosing a capillary providing capillary action as the motive force for transferring sample fluid across the test surface.

Regarding the recited limitations that the housing comprises a second channel and second opening, Oberhardt discloses that his invention may be modified in light of his disclosure and further it has been held that "mere duplication of parts has no patentable significance unless new and unexpected result is produced." *In re Harza*, 124 USPQ 378. Furthermore, it would have been obvious a person of ordinary skill in the art to incorporate additional channels and openings to Oberhardt's invention because it would be desirable and more efficient to have a plurality of channels and openings to allow more than one sample to be analyzed simultaneously, or alternatively, it would allow one sample to undergo multiple analyses simultaneously.

#### **Response to Arguments**

9. Applicant's arguments filed on 4/19/07 have been fully considered but they are not persuasive.

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In response to applicant's argument that Oberhardt does not indicate "a second channel positioned to remove unreacted sample from the first chamber" because Oberhardt does not remove liquid sample from the reaction chamber, examiner disagrees. Oberhardt discloses that his invention may be modified and varied in light of his disclosure. See for example, figures 11A(1)-11C, which depict a plurality of channels. Furthermore, mere duplication of parts has no patentable significance unless new and unexpected result is produced. As to the language reciting, "to remove unreacted sample from the first chamber," Oberhardt reads on such language is a recitation of the intended use of the claimed invention. To patentably distinguish the claimed invention from the prior art, the claimed invention must result in a structural difference between the claimed invention and the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, the structure disclosed by Oberhardt is fully capable of performing the presently recited operation.

In response to applicant's argument that Oberhardt does not have "means for inducing a negative pressure differential on the sample to direct the sample through the first channel, into the chamber, to the test surface, and to thereafter remove an unreacted portion of the sample from the test surface and into the second chamber" because Oberhardt does not remove any sample from its reaction chamber and does not have a second chamber, examiner disagrees. Oberhardt's discloses in column 6, lines 30-38 and column 17, lines 28-44, for example, a syringe, which is capable of performing the presently recited operation. As to the second chamber, as stated above, Oberhardt discloses that his invention may be modified and varied in light of his disclosure. See for example, figures 11A(1)-11C, which depict a plurality of

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channels. Furthermore, mere duplication of parts has no patentable significance unless new and unexpected result is produced.

In response to applicant's argument that Oberhardt does not teach the function of having a test strip that is removably attached to a housing, it is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, the structure disclosed in figures 3 and 11C, for example, by Oberhardt are fully capable of performing the presently recited operation.

In response to applicant's assertion that Examiner acknowledged the failure of Oberhardt to disclose the multiple limitations in the recited claims, examiner disagrees. As stated in Office action, filed on 12/15/06, examiner pointed out that Oberhardt anticipates having additional channels because Oberhardt discloses that his invention may be modified in light of his disclosure. Oberhardt discloses such modification of his device in figure 3 by disclosing in figures 11A(1)-11C, a plurality of channels.

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1743

  
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